SUBCUTANEOUS Rituximab (MabThera) Maintenance

INDICATION: Maintenance therapy in low-grade follicular NHL

Maintenance Therapy every 2 months until disease progression or for a maximum period of two years (12 doses) in first line follicular NHL (NICE TA226)

OR Every 3 months until disease progression or for a maximum period of two years (8 doses) in relapsed / refractory follicular NHL (NICE TA137)

Subcutaneous product only to be used as a single agent. Not to be given with other chemo-therapeutic agents. If Rituximab is being administered as part of a chemotherapy regime, it must be given in the intra-venous (IV) form instead.

Prior to a course of treatment

- **Before starting subcutaneous rituximab, all patients must always receive beforehand, a full dose of rituximab by intravenous infusion, using the intravenous formulation.**
- **If patients were not able to receive one full rituximab intravenous infusion dose prior to the switch, they should continue the subsequent cycles with rituximab intravenous formulation until a full intravenous dose is successfully administered.**
- Sub cutaneous rituximab is contraindicated if prior use of intra-venous rituximab has led to anaphylaxis, hypotension requiring stopping of the IV infusion or hypersensitivity reactions requiring IV hydrocortisone. Patients must have received a full dose of IV rituximab first, safely
- Written consent for course

Prior to each dose

- Medical review of fitness for chemotherapy – exclude active infection, major changes in organ function.
- Clinician to assess if there have been recurrent sepsis episodes. If so check serum Immunoglobulin levels and treatment should be reviewed.
- FBC. Caution should be exercised when considering treatment of patients with neutrophils < 1.0 x 10^9/l
- Premedication consisting of analgesia and an antihistamine should always be administered 30 minutes before each infusion of rituximab. (e.g. paracetamol 1g oral STAT and chlorphenamine 4mg oral).
- If the patient develops a severe reaction to rituximab, consider the appropriateness of continuing subcutaneous therapy versus switching back to intravenous therapy. If subcutaneous dosing is continued, add 30mg prednisolone orally 30 minutes prior to all future subcutaneous rituximab doses. At discretion of consultant.
- MabThera subcutaneous formulation should be injected subcutaneously into the abdominal wall and never into areas where the skin is red, bruised, tender, hard or areas where there are moles or scars. No data are available on performing the injection in other sites of the body, therefore injections should be restricted to the abdominal wall.

Chlorphenamine	4mg	Oral 30 minutes prior to rituximab
Paracetamol	1g	Oral 30 minutes prior to rituximab
Rituximab SUBCUTANEOUS formulation	1400mg	Subcutaneous injection over approx. 5 minutes

Repeat cycle every 2 -3 months until disease progression or for a maximum period of two years (8 - 12 doses, see under indications above)

Please note that there are TWO different formulations of rituximab (Intravenous AND Sub-cutaneous). ALWAYS confirm the intended route of administration and prescribe using the appropriate order-set

Patients should be observed for at least 15 minutes following subcutaneous injection
If an injection is interrupted it can be resumed at the same site or another location may be used, if appropriate

Prophylaxis for acute emesis - NIL

Prophylaxis for delayed emesis - NIL

Other medications

NIL

Dose modifications

No modifications to sub-cutaneous dose. One standard dose only

Discontinue subcutaneous route if poorly tolerated by patient. IV route may be preferable

Contraindications
- Hypersensitivity
- Severe immunocompromise
- Severe active infections

Toxicities

Hypersensitivity (but all patients should have had at least one safely administered dose of iv rituximab already). Fever, hypotension, rigors, anaphylaxis, but rare if safely administered intra-venously first.

Local site reactions: pain, erythema, rash, pruritis

Increased bacterial infections, increased risk of shingles and other herpes infections, risk of hepatitis B and C reactivation, progressive multifocal leucoencephalopathy

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